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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,751	11/02/1998	WOLFGANG-M. FRANZ	690-110PCT	2640

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/068,751	FRANZ ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-2-04, 5-17-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *non-compliance notice*.

DETAILED ACTION

This Office action is in response to the communication filed 6-24-05.

Claims 83-124 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Please provide a SEQ ID NO. for the sequence in Figure 10).** See the accompanying Notice to Comply.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 83, 84, 86 -124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention for the reasons of record set forth in the Office action mailed 1-25-05.

In claim 83, lines 7-9, it is still unclear what is encompassed by "nucleotides of approximately residue –19 to approximately residue –800, with respect to the transcription starting point, which corresponds to nucleotide 2406 of SEQ ID NO: 1." It also remains unclear in claims 122 and 123, lines 2-3, what is meant by "nucleotides –19 to –2700, with respect to the transcription star[t]ing point, which corresponds to nucleotide 2406 of SEQ ID NO: 1." (What SEQ ID Nos. are the regions comprising "approximately nucleotides –19 to approximately residue –800" (claim 83) and "nucleotides –19 to –2700" (claims 122-123) referring to?) Appropriate clarification is required.

The metes and bounds of the terms "corresponding to" and "approximately" cannot be determined (*e.g.* see claim 83, lines 5-6; claim 84, line 6; claim 91, lines 8, 10, 12, 16; claim 92, line 3; claim 93, lines 8, 10, 12 and 16). Appropriate clarification is required.

Applicant's arguments filed 6-24-05 have been fully considered but they are not persuasive. Applicants argue that the term "corresponding to" fully apprises one of ordinary skill in the art of molecular biology of the scope of the claimed invention. Applicants also argue that this term is used frequently in the art of molecular biology to describe a relationship between aligned sequences. Applicants are correct that the term *corresponding to* is frequently used in molecular biology communications. But, contrary to Applicants' assertions, claim language is more stringently scrutinized than

phrases that are routinely published in scientific communications to convey a concept. Scientific publications are written to exchange information and to convey and review the latest scientific findings, not to exclude others from making and using a defined invention for the duration of a patent term. The claims, on the other hand, are required to contain clear, concise, and exact terms - adequately describing what is embraced by the instant invention. The terms "corresponding to" and "approximately" are vague and may encompass an indeterminate number of variations, and read on a vast array of nucleotide sequences.

Claims 83, 84, 86 -124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 1-25-05.

Applicant's arguments filed 6-24-05 have been fully considered but they are not persuasive. Applicants argue that the term "corresponding to" fully apprises one of ordinary skill in the art of molecular biology of the scope of the claimed invention. Applicants also argue that the alignment of MLC-2 promoters from human, mouse and rat, and the conserved homology between the three promoters provide adequate description for the claimed invention. Contrary to Applicants' assertions, providing alignments of three known sequences does not adequately describe the genus comprising any promoter nucleic acid fragment of a mammalian myosin light chain-2 gene corresponding to nucleotides of SEQ ID NO: 1. The specification teaches methods of making a recombinant adenoviral or adeno-associated viral vector comprising two terminal repeat sequences of said viruses and packaging signal of said

viruses, and a functional mammalian myosin light chain-2 (mlc2) gene comprising the nucleotide sequence described in Figure 10, SEQ ID NO: 1. The mlc2 promoter of SEQ ID NO: 1 is not representative of the very broad genus comprising any mammalian myosin light chain 2 gene promoter fragment corresponding to the sequences cryptically depicted in the language of the claims (e.g. "comprising nucleotides of approximately residue –19 to approximately residue –800..., which corresponds to nucleotide 2406 of SEQ ID NO: 1"). This very broad genus reads on a myriad of possible sequences, and the homology depicted in the alignments between three species of the genus does not provide the requisite, concise descriptions to adequately describe the genus claimed. The structure function information in the prior art provides a general description of consensus sequences and some conserved residues between various mlc2 promoters, but this information does not adequately address the question of what sequence fragments are required for promoter activity, and which sequences relative to the claimed sequences of SEQ ID NO: 1 provide promoter activity in the recombinant vectors claimed. No other promoter fragment has been described that provides promoter activity (see also page 21, first full paragraph of the instant disclosure: "It is concluded that the mlc 2 promoter in neonatal cardiomyocytes is active, while the expected activity of the smmhc promoter in neonatal and adult smooth muscle cells was missing."). This illustrates that, despite the disclosure of general promoter elements that are present in the various promoter sequences, the concise description of sequences necessary for promoter activity in the claimed fragments is lacking. The disclosure of a single promoter sequence or fragment thereof that provides promoter

activity in the constructs claimed is not representative of the genus. For these reasons, the instant rejection for lacking adequate written description is maintained.

Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure for the reasons of record set forth in the Office actions mailed 10-30-03 and 1-25-05. See *In re Mayhew*, 527 F2d 1229, 188 USPQ 356 (CCPA 1976).

No arguments were made addressing this rejection for lacking a deposit of biological materials, as set forth in the Office action mailed 10-30-03.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

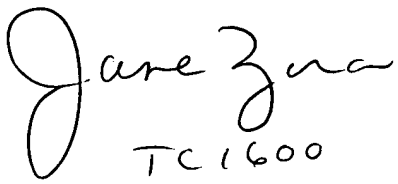
Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ɜ 1.6(d)). The official fax telephone number for the Group is **703-872-9306, or after July 15, 2005, the new fax telephone number is 571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
8-25-05



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NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Please Provide A SEQ ID No. For Figure 10.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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